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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:
Shannon
Serial No. 09/690,173

Filed: October 16, 2000

For: Method for Linear mRNA
Amplification

Art Unit:

Examiner: Janet Epps

Atty Docket No. 10990638-2

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REPLY
Brief

Assistant Commissioner for Patents
Washington, DC 20231

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REPLY BRIEF

INTRODUCTION

The following Reply Brief is submitted in response to the Examiner's Answer dated January 9, 2003.

In the Examiner's Answer, the Examiner rebutted the positions put forth by the Applicant in the Appellant's Brief filed October 15, 2002 for several reasons. In the following Reply Brief, the Appellant first demonstrates why the Examiner's reasons for rebuttal are insufficient. The Appellant then reiterates the relevant law concerning printed matter and applies the law to the claims of the present application to demonstrate that the claims are patentable over the cited references.

EXAMINER'S REASONS FOR REBUTTAL

In the Examiner's Answer, the Examiner rebuts the Appellant's position for the following reasons:

- 1) That the printed matter is merely a recitation of use and carries no patentable weight under MPEP § 2111.02;
- 2) That the instructions do not confer any structural or functional interrelationships between the other aspects of the kit and therefore pursuant to MPEP § 2106 IV.B.1(b) do not carry any patentable weight;

- 3) That the prior art structure is capable of performing the intended use and therefore under MPEP § 2115 the instructions carry no patentable weight; and
- 4) That the instructional element does not impart novelty to the kits.

Each of the above rebuttal reasons is now shown to be insufficient overcome the Appellant's position.

Reason 1

As summarized above, the Examiner first states that the instructional element of the pending claims do not carry patentable weight because they are merely considered to be an intended use recitation of the composition of the claims. In support of this position, the Examiner cites to MPEP § 2111.02.

However, MPEP § 2111.02 is directed to words appearing in the preambles of claims, not to elements appearing in the bodies of claims. MPEP § 2111.02 is titled "Weight of Preamble" and is solely directed to whether or not words appearing in the preambles of claims carry any patentable weight. This section teaches that a recitation of an intended use in a preamble may not carry patentable weight. However, this section is completely silent on whether instructional material that is in the body of the claim carries any patentable weight.

The Examiner has cited no authority for treating the instructional material element of the body of the pending claims the same as a recitation of intended use in the preamble of a claim. In the absence of any such cited authority, it is respectfully submitted that the Examiner is incorrectly treating the instructional element of the pending claims the same as a recitation of use that would appear in the preamble of the claim.

As such, the Examiner's position that the instructional element carries no patentable weight because it is the same as a preamble recitation of use is not correct and should be withdrawn. The cited MPEP § 2111.02 does not teach that an instructional element in a kit is the same as a recitation of use in a preamble or can be treated the same as a recitation of use in a preamble. As such, the cited MPEP § 2111.02 does not support the Examiner's position.

Reason 2

As summarized above, the Examiner has also taken the position that the instructions do not confer any structural or functional interrelationships between the other aspects of the kit and therefore pursuant to MPEP § 2106 IV.B.1(b) do not carry any patentable weight. The cited MPEP § 2106 IV.B.1(b) is directed solely to descriptive material that is present by itself on a computer readable medium. It is not directed to the situation where the instructions are present as a separate physical element in addition to other physical elements, e.g., reagents, in a claimed kit combination.

As shown in the Appellant's brief and reiterated below, the instructions do impart functionality to the other components of the pending claims of the present application. Since the cited MPEP § 2106 IV.B.1(b) is directed to data on a computer readable medium and not instructions in a kit of reagents, it does not teach otherwise. As such, this cited MPEP § 2106 IV.B.1(b) does not support the Examiner's position that the instructional element of the claims fails to carry any patentable weight because this section is directed to a completely different type of subject matter.

Reason 3

The Examiner has also stated that the prior art structure is capable of performing the intended use and therefore under MPEP § 2115 the instructions carry no patentable weight. However, the cited MPEP § 2115 is specifically not applicable to kit claims. MPEP § 2115 teaches in part:

"Note that this line of cases is limited to claims directed to machinery which works upon an article or material in its intended use. **It does not apply to product claims or kit claims** (i.e., claims directed to a plurality of articles grouped together as a kit.)"

As is clear from the above quote, the cited MPEP § 2115 specifically does not apply to kit claims and therefore does not support the Examiner's refusal to afford any patentable weight to the instructional element of the pending claims.

Reason 4

Finally, the Examiner has asserted on the last page of the Examiner's Answer that the instructional element does not impart any novelty over what is described in the cited Phillips and Wang references. However, the instructional element of the pending claims incorporates the method claims of issued patent 6,132,997, which issued patent was allowed over both Phillips and Wang, notably by the same Examiner. As such, the Examiner has already found that the method recited on the instructional element of the claimed kits is patentable over the cited Phillips and Wang references, and cannot now hold contrary to this earlier finding. As such, the Examiner has already determined (as evidenced by the issuance of U.S. Patent No. 6,132,997) that the method recited in the instructional element of the claimed kits is patentable over anything described in the cited Wang and Phillips references.

As can be seen from the above discussion, each of the Examiner's reasons for rebutting the Appellant's previous showing that the instructional material is to be accorded patentable weight is insufficient to overcome the Appellant's position.

THE PENDING CLAIMS ARE NOT ANTICIPATED BY WANG ET AL. NOR PHILLIPS ET AL., BECAUSE THE CLAIMED ELEMENTS DIRECTED TO PRINTED MATTER CARRY PATENTABLE WEIGHT, AS A RESULT OF THE FUNCTIONAL RELATIONSHIP BETWEEN THE CLAIMED ELEMENTS DIRECTED TO PRINTED MATTER AND THE OTHER CLAIMED ELEMENTS.

The following section summarizes the law regarding printed matter and applies the law to the present situation to demonstrate that the instructional material of the present claims is to be afforded patentable weight.

The Printed Matter Doctrine

The law provides guidance on the issue of the patentable weight of printed matter. Printed matter by itself does not constitute a "manufacture" and is not within the statutory classes of patentable subject matter. [M.P.E.P. §706.03(a)]. However, as an exception to this rule, printed matter may constitute an element of a patentable claim if the claim element involves a new and useful feature of a physical structure or if the claim involves a **new and**

useful relation between the printed matter and a physical structure. [*Chisum on Patents*, §1.02(4), p.1-20.]

“[It is] well settled that patentable weight can be given printed matter only when a novel relationship exists between said printed matter and the claimed structure.”
[*In re Miller*, 418 F.2d 1392, (C.C.P.A. 1969).]

Printed Matter constitutes a limitation upon which patentability may be predicated

The court in *In re Lowry*, 32 F.3d 1579, (Fed.Cir. 1994), has taught that that:
“The [PTO] must consider all claim limitations when determining patentability of an invention over the prior art. The PTO may not disregard claim limitations comprised of printed matter.”
[*In re Lowry*, 32 F.3d 1579, 1582 (Fed.Cir. 1994).]

As such, the Examiner cannot ignore the printed matter element of the instructions for use in the instant invention and then reject the application based on anticipation of the claims without the printed matter. Specifically, the Examiner must consider claim limitations comprised of printed matter when the claim is directed to a combination of elements. As the court in *In re Miller* stated:

“The fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination.”
[*In re Miller*, 418 F.2d 1392, 1396 (C.C.P.A. 1969).]

Further the court in *In re Gulack* also stated:

“Differences between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter. [The Examiner] cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. **The claim must be read as a whole.**” [emphasis added]

“...the CCPA notably weary of reiterating this point, clearly stated that printed matter may well constitute structural limitations upon which patentability can be predicated.”
[*In re Gulack* 703 F.2d, 1381, 1385 (Fed. Cir. 1983).]

The Applicants do not seek to patent the content of information inside the instructions themselves alone, but rather, the combination of elements in the kit as a whole, leading to the new and useful application of reagents imposed by the instructions. Thus, the Examiner must regard the printed matter elements of the instant claims as a limitation upon which patentability may be predicated.

The location of the printed matter is immaterial

Furthermore, the printed matter does not have to be directly printed on the remaining claimed structural elements to confer functionality to the claimed invention. The printed matter of the subject invention directly affects the material properties of the remaining structural elements of the kit, regardless of the location of the printed matter (even though not directly printed on the remaining structural elements). The Court in *In re Miller* specifically noted that the specific location of the printed matter was immaterial to their functionality. It is the functional relationship between the printed matter and the other elements, and not their structural relationship that is significant.

The invention in *In re Miller* involved an element of a measuring receptacle and another element of a legend. The court noted that the element of the legend was either “on the receptacle *or* attached to it...” [emphasis added], [*In re Miller*, at 1394.] Thus the printed matter (legend) of the invention in *In re Miller* was not necessarily “directly printed upon the claimed invention.”

Further, the court in *In re Miller* stated:

“While the examiner was quite willing to consider such elements as proper parts of the ‘structure’ and in ‘a definite structural relationship with the wall of the measuring vessel’ when, as in the allowed claims, they were required to be in ‘a specific location,’ he would give them no weight at all, apparently, when the location was not specified or necessarily restricted... We do not see why this is so and the examiner does not tell us. We do not see the ‘structural’ relationship – whatever that means – is required to obtain the practical, problem-solving results of the appellant’s invention...It seems to us that **what is significant here is not structural but functional relationship...**” [emphasis added]; [*In re Miller*, at 1395-6.]

Thus the cases of *In re Gulack* and *In re Miller* teach that the location of the printed matter of the subject invention is immaterial to its functionality. The instructions of the subject invention impart a new and useful functionality to the reagents apart from its structural relationship to the reagents or its specific location within the kit.

Functional Relationship

As per the printed matter doctrine, the critical question is whether there exists any new and useful functional relationship between the printed matter and the other structural elements of the claims (reagents). As the court in *In Re Levin* stated:

“The only requirement that 35 U.S.C. §101 imposes as set forth in *In re Miller* is that a new and unobvious functional relationship must exist between the claimed combination of printed matter and other claimed elements.”

[*In re Levin*, 1997 U.S. App. Lexis 1781, (Fed. Cir. 1997).]

The Examiner in the instant case has rejected the Applicant's arguments that there is such a functional relationship. Specifically, the Examiner based her rejection on the reasoning that “[t]he printed material of the kit of the instant invention, do not directly affect any material properties of the remaining contents of the kit.” However, with respect, it is submitted that the Examiner erred in her analysis, and it is respectfully submitted that the printed material elements of the instant invention do in fact directly affect the remaining elements of the kit, and are thus functionally related.

As noted in the above discussion with respect to the case of *In re Lowry* and the printed matter doctrine, it makes no difference that the printed matter is processed by a mind. As long as there is a functional relationship between the printed matter and the remaining elements of the claim, the printed matter will be accorded patentable weight. Thus it is submitted that the instructions for use of the instant invention, although not processed by the reagents of the kit, (like software is processed by a computer), nevertheless, carries patentable weight.

The court in *In re Lowry*, (assuming arguendo that data objects and data structures were analogous to printed matter) found that the data objects (as printed matter) were functionally related to the computer memory (claimed structural element). The court reasoned that the data objects (printed matter), although existing only as:

“a collection of bits having information about relationships between the ADOs,...facilitated addition, deletion, and modification of information stored in the memory. In sum, the ADO’s **perform a function**. Gulack requires no more. See *Gulack*, 703 F.2d at 1386.”

[*In re Lowry* at 32 F.3d 1579, 1583-4 (Fed. Cir. 1994).]

Thus the court found a functional relationship based on the finding that the printed matter performed a function within the invention.

The court in *In re Miller* found a functional relationship between the printed matter and other elements of the claims, although the printed matter was not processed by, nor directly located on the remaining structural elements. There the invention involved a structural element directed to a measuring receptacle, and a printed matter element directed to a legend specifying the ratio or proportion of a full recipe to be measured in the said measuring receptacle. In concluding a functional relationship between the legend and the receptacle, the court stated:

“Here there is a new and unobvious functional relationship between a measuring receptacle, volumetric indicia thereon indicating volume in a certain ratio to actual volume, and a legend indicating the ratio, and in our judgment the appealed claims properly define this relationship.”

[*In re Miller*, 418 F.2d 1392, 1396 (C.C.P.A. 1969).]

The printed matter element of *In re Miller*, performed a function of directing how to use the other elements of the claim in a way that was different from the prior art. As a result, the court found that there was a functional relationship between the printed matter element and the remaining structural element.

Further, the case of *In re Levin* is also instructive. The invention in that case involved a coding system for visually displaying a color code uniquely signifying the expiration date of each of a plurality of pharmaceutical products. The color coded indicia (printed matter element) provided information about the pharmaceutical product (structural element). The court in observing that the color coded expiration date indicia provides information about the pharmaceutical product or what is contained in it, found that "the relationship between the expiration date indicia on the container or pharmaceutical product is a functional relationship." [*In re Levin*, 1997 U.S. App. Lexis 1781.]

The claims of the instant invention are directed to, *inter alia*, a kit containing (i) biochemical reagents; and (ii) instructions for use of the reagents in a specific method. The instant invention involves the application of the reagents, as directed by the instructions for use, in a method that the prior art neither discloses nor suggests. The reagents are uniquely treated, arranged and combined as per the instructions for use. The instructions for use exist as a collection of information that perform a function by facilitating the specific treatment, arrangement and combination of the reagents of the kit in a new and useful way. (as did the data objects of the invention in *In re Lowry*, by facilitating the addition, deletion, and modification of information stored in memory.) The instructions for use impart a tangible functional consequence in the improved method of linearly amplifying antisense RNA by providing information on how to use the reagents of the kit in a new and useful manner (as did the color coded indicia of the invention in *In re Levin*, by providing information about the expiry date of the pharmaceutical product). Accordingly, the elements directed to the instructions for use are dynamic and functionally significant elements of the instant kit claims, and not just mere passive or descriptive recordings of information or mere compilations of facts. The instructions for use perform a determining function of directing a new and useful method of applying the reagent elements. (as did the legend of the invention in *In re Miller*, in specifying the ratio or proportion of a full recipe to be measured in the measuring receptacle.) As per the court's reasoning in *In re Lowry* noted above, the law requires no more than the performance of a function.

Furthermore, there is a definite and decided relationship between the reagents and the instructions for use. The manner of application of the reagents depends on the instructions for use. There is a cooperative relationship between the instructions for use and the reagents of the kit, without which it would be impossible to carry out the improved method of antisense

RNA amplification. It is submitted that without the instructions, one skilled in the art would not know how to use the reagents of the kit in the improved method of antisense RNA amplification. As such, the instructions for use do not merely provide an intended use of the reagents, but are functionally related to the reagents of the kit because they specifically direct how to apply them. The instructions are an integral and necessary element of the kit in that the reagents can only be used effectively with them. By virtue of this unique functional relationship between the instructions and the reagents, great savings of time and money are effected by the use of this improved method of antisense RNA amplification (i.e. fewer steps are required in antisense RNA amplification, resulting in less required labor; and the method is amendable to robotic handling). Thus the combination of the instructions and reagent elements of the subject invention and the functional relationship that exists between them, is a new and useful inventive concept that must be accorded patentable weight.

Claims 32-48 considered in their entirety (including the printed matter elements with patentable weight), are not anticipated by the references of Wang et al. and Phillips et al.

The Examiner has asserted that the instant claims, even assuming that they carried the patentable weight of the printed matter, are anticipated by the Wang et al. and Phillips et al. references. Specifically, the Examiner stated: "[a]ssuming, *arguendo*, that the instructions of the present invention functionally modified the claimed invention, one of skill in the art would recognize that the disclosures of the Wang et al. and Phillips et al. references can be used as a set of instructions to use the contents of the kit of the present invention in a method of mRNA amplification." Further, the Examiner has asserted that the Applicants "have not explicitly stated how the method suggested by either Wang or Phillip is distinct from the intended use of the kit of the claimed invention."

It is respectfully submitted that the Examiner has erred in her analysis. The teachings of Wang et al. and Phillips et al. are concerned with completely different methods, as evidenced by the issuance of the methods of the present kits in the parent application, which parent application issued as Patent No. 6,132,997 over both Wang and Philips. Specifically, the methods disclosed in Wang and Phillips require a phenol/chloroform extraction step to remove the reverse transcriptase prior to second strand cDNA synthesis. Accordingly, transcription of cDNA into RNA in the Wang and Phillips methods does not occur in the presence of a reverse transcriptase, since the reverse transcriptase has been removed by the prior phenol/chloroform extraction step. As such, the methods disclosed by Wang and

Phillips are completely different from the methods appearing in the instructional element of the claimed kits, since the subject methods are ones where RNA is transcribed from cDNA in the presence of a reverse transcriptase. The fact that the methods of the instructions of the present kits per se were found patentable over the both Wang and Philips in the parent application evidences that the methods of Wang and Philips neither anticipate nor obviate the methods disclosed in the instructions of the present kits. Thus neither Wang's nor Philips' disclosures could be "used as a set of instructions to use the contents of the kit of the present invention in a method of mRNA amplification", as specified in the instructions of the present kits.

It is well established that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." [*Verdegaal Bros. V. Union Oil of California*, 2 USPQ 2d 1051 (Fed. Cir. 1987), *cert denied*, 481 U.S. 1052 (1987); *See also Scripps Clinic and Research Foundation v. Genentech Inc.*, 18 USPQ 2d 1001, (Fed. Cir. 1991).] As such, any art cited must describe a kit containing reagents and an instructional element to use the reagents in the recited method, (as was patented in the parent application).

In the instant case, Wang fails to teach a kit containing the instructional element of the present claims because Wang is concerned with an entirely different method, i.e., one that includes a phenol/chloroform extraction step, as discussed above. As such, Wang fails to teach each and every element of the claims. Because Wang fails to teach each and every element of the claimed kit, e.g., the instructions, Wang fails to anticipate Claims 38 and 41-48 under 35 U.S.C. § 102(e).

Further, Claims 32-36 and 39-40 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Phillips. Again, this reference fails to teach a kit containing the instructional element of the present claims because Phillips is concerned with an entirely different method, i.e., one that includes a phenol/chloroform extraction step, as described above. As such, Phillips fails to teach each and every element of the claims. Because Phillips fails to teach each and every element of the claimed kit, e.g., the instructions, Phillips fails to anticipate Claims 32-36 and 39-40 under 35 U.S.C. § 102(b).

Having established that the printed matter element carries patentable weight, the instant kit claims considered in their entirety, are thus not anticipated by the references of Wang et al. and Phillips et al.

SUMMARY

The above discussion demonstrates that the instructional elements of each of the instant claims carry patentable weight because there is a functional relationship between the instructional elements and the reagent elements. As demonstrated above, each of the Examiner's reasons for rebutting the above position are not supported by the law and therefore are insufficient to overcome the above position. It is noteworthy that the Examiner has been unable to cite to any cases or rules which govern instructional components of claimed kits to support the Examiner's position. The absence of any such case law or rule support clearly demonstrates that the Examiner is incorrectly applying the law in the present case.

The instant claims are not anticipated by Wang et al. and Phillips et al. because the said references each fail to teach the elements of the instant claims that are directed to the instructions for using the reagents in a novel method of linear mRNA amplification. As such, none of the pending claims are anticipated by Wang et al. or Phillips et al. and are patentable over these cited references.

RELIEF REQUESTED

Appellants respectfully request that the rejection of Claims 32-48 under 35 U.S.C. §102(b) and 35 U.S.C. §102(e) be reversed and that the application be remanded to the Examiner with instructions to issue a Notice of Allowance.

Respectfully submitted,

Date: 3.10.03


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